

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Yong D. Zhao Examiner: Alter, Alyssa M.
Serial No. 10/668,789 Group Art: 3762
Filing Date: September 23, 2003 Docket No.: P0010040.00
Title: MEDICAL ELECTRICAL LEAD SYSTEM INCLUDING PRE-FORMED
J-SHAPED STYLET

Pre-Appeal Brief request for Review

MAIL STOP Appeal Brief
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the outstanding Final Office Action dated April 29, 2011 and the Advisory Action dated August 25, 2011 in the above-identified application.

A Notice of Appeal is submitted herewith. An Appeal fee has previously been paid. Any additional fees owing due to the recent fee increase will be paid with filing.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

Argument

All claims were rejected under 35 U.S.C. 103 as being obvious over Dutcher (US 4,381,013) in view of Evans, III, et al. (US 4,854,330). This rejection is again respectfully traversed.

In the Advisory Action, the Examiner once again disputes the facts underlying Applicants' arguments rather than disputing the arguments as based upon those facts.

Respectfully, the Examiner has simply got the facts wrong.

In the Advisory Action, the examiner now argues as follows:

However, Dutcher discloses in col. 3, lines 50-52, "This bend is preferably "J" shaped for insertion of the body implantable lead into the atrium." Therefore the examiner refutes the Applicants contention that the "preformed curve in Dutcher is intended to hold the distal tip of the lead stationary" (see Arguments page 8). Dutcher states that the "J-shape" is used to navigate the vasculature during insertion of the lead in the atrium. Thus the contention that Dutcher utilizes the J-shape or preformed curve to hold the tip stationary against the tissue wall is not a correct assertion.

With all due respect, the Examiner's above assertion is both incorrect and irrelevant.

The irrelevant part of the above argument is that the j-shaped stylet is used to navigate the lead through the vasculature. Of course it is. All stylets perform this function. This doesn't mean that the j-shaped stylet isn't also used to hold the tip of the lead stationary during rotation of the helix into the tissue.

The incorrect part of the argument is that the j-shaped stylet is in fact also used to hold the tip of the lead stationary against the wall during rotation of the helix.

In the Abstract of Dutcher, it states:

"The distal end of the body implantable lead is located in the position desired through the use of the solid inner first portion of the stylet in which a bend or other desired shape has been introduced."

The j-shape of the stylet thus holds the distal end of the lead body in the desired location. The desired position is of course the tissue in which the electrode is desired to be placed.

The Abstract goes on to state:

"The body implantable lead is permanently attached to the muscle tissue by a fixation device activated through the torque supplied by the second portion of the stylet."

Rotation of the fixation device to attach it to the tissue necessarily occurs at the desired position. It thus occurs by rotation of the outer stylet around the j-shaped stylet.

Since the outer portion of the stylet is rotating around the j-shaped stylet, the inner j-shaped portion of necessity is maintaining the distal tip at that location. If the distal end wasn't maintained in this location, the helix wouldn't get screwed into this location.

The j-shaped stylet is disclosed as intentionally made more rigid than the lead body in the curved region and the outer stylet taken together. This is necessarily so because it causes the lead body to assume the j-shaped configuration. This is also why the outer stylet can transmit torque undiminished around the j-shaped curve of the inner stylet without dislocating the distal tip of the lead from the desired location.

Applicants respectfully cannot believe that any of the above can possibly be controversial.

The Examiner further argues as follows:

Additionally, Dutcher discloses "FIG. 6 is a cross-sectional view of the two-piece stylet as assembled. Notice that distal tip 34 of solid stylet wire 30 is foreshortened. Notice also that torque induced by the implanting physician by turning knob 38 is transmitted via coil 40 to torque transmission tool 44, without regard to the shape of solid stylet wire 30"(col. 4, lines 18-23). Thus, as explained by Dutcher above, the shape of the stylet 30 does not affect the torque administered to the system(col. 4, lines 18-23). And as such, the curvature does not affect the transmission of torque in the system. Therefore, the Applicant's argument that the curve of the stylet 30 has to be "the least flexible portion" and tapering the stylet "would thus directly interfere with its functionality" is not consistent with the disclosure of Dutcher since the curvature is to navigate the vasculature during implantation.

With all due respect, the Examiner's above argument is also irrelevant and erroneous.

The irrelevant part of the argument is that the torque is transferred regardless of which shape is chosen for the stylet. This observation is irrelevant because it does not respond to or refute any argument presented by Applicants and has nothing whatsoever to do with whether the tip of the lead stays put during the rotation of the helix. Whatever configuration is chosen for the inner stylet, it is still intentionally the stiffest part of the assembly and still has to hold the tip stationary at the desired location during rotation of the stylet.

Further, the Examiner's entire argument for rejection of the claims is expressly based upon the Dutcher stylet having the described j-shaped configuration. How the lead might work with other curved configurations is actually irrelevant to the Examiner's express grounds for rejection.

Finally, the erroneous part of the above argument is the express argument that holding the tip of the lead in place and navigating it through the vasculature are somehow inconsistent. Respectfully, this is nonsense. The j-shaped stylet as disclosed has to do both things. The j-shaped curve of the inner stylet is specifically designed to be the most rigid structure along the distal portion of the lead. It is expressly disclosed as being rigid enough to impart its curvature to both the lead body and the outer stylet. Making it less rigid by means of adding a taper along this curve is directly contrary to the express requirement that it is the most rigid part of the assembly.

As discussed in the response to the Final Office Action, the j-shaped inner stylet must be sufficiently rigid to maintain the j-shape at the implant site while the outer stylet is torqued around it. The outer stylet has no pre-set curvature. Therefore, as it is rotated around the j-shaped curve, it necessarily frictionally imparts torque to inner stylet, tending to deflect it. This is basic physics and there can be no reasonable basis to dispute this fact.

If the torque applied by the outer stylet deforms the curvature of the inner stylet, the distal end of the lead will move. Again, this is basic physics and there can be no

reasonable basis to dispute this fact. The j-shaped portion of the inner stylet must be rigid enough to withstand deformation due to this applied torque. Otherwise, the efficient transmission of torque as discussed by the examiner would be of no avail. Making it less rigid by tapering it over the j-shaped portion is therefore directly contrary to the basic teaching of Dutcher.

The Examiner does not actually dispute Applicants' arguments. She instead erroneously disputes the facts underlying Applicants' arguments. Respectfully, this cannot possibly be a valid basis to uphold an obviousness rejection.

Nothing in Evans addresses the above arguments or counters the teaching of Dutcher.

The issues are clear. The Fees have been paid, with the exception of the fee increments. The Appeal Brief is essentially written. The Examiner is requested to either allow the application or let it go up on appeal.

With allowance of claims 1 and 17, the withdrawn claims dependent thereon should also be allowed. Allowance of withdrawn claims 9 – 16 and 24 – 30 is therefore also respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

September 26, 2011
Date

/Reed A. Duthler/
Reed A. Duthler, Reg. No. 30,626
(763) 526-1564
Customer No. 27581